WASHINGTON, DC— To authorize necessary regulations of the sale and distribution of tobacco products, Congressman Sestak co-sponsored and helped pass HR 1256, the Family Smoking Prevention and Tobacco Control Act. The bill was approved by the House 307-97 and awaits President Obama's signature. As a result of this legislation, the Food and Drug Administration (FDA) gains greater authority to reduce access to, advertising of, and promotion of these products, as well as adopt rulings that it believes are "appropriate to protect the public health."

"As a father, it is of upmost importance to me that we discourage teenage smoking," said Congressman Sestak. "By limiting marketing to children and removing tobacco products specifically marketed to kids we can prevent some of the 3,500 children who try cigarettes for the first time every day from falling into an addictive and dangerous habit."

Tobacco manufacturers will be required to disclose the contents of and list harmful ingredients in their current products and prior to introducing new products. The bill prevents inappropriate marketing of modified risk tobacco products, typically marketed as "light," "mild," or "low." Tobacco companies can only use these descriptions if evidence suggests the product significantly reduces the risk of tobacco-related disease. In addition, the bill requires the FDA to examine ways to regulate products that promote abstinence from tobacco use, reductions in consumption, and reductions in the harm associated with tobacco use. This would facilitate expanded health insurance coverage of effective cessation treatments for those addicted to tobacco.

The bill fully funds FDA tobacco activity through user fees on tobacco product manufacturers.

Specific Provisions of HR1256, The Family Smoking Prevention and Tobacco Control Act

Restrictions on Sale of Tobacco Products

The measure authorizes the FDA to issue regulations restricting the sale and distribution of tobacco products, including access to, advertising, and promotion of those products, if the

agency determines that the regulations would be "appropriate to protect the public health." The measure specifically authorizes the FDA to impose restrictions on the advertising and promotion of tobacco products within retail establishments that limit admittance to persons over 18 years of age.

Prohibition on Flavored Cigarettes

This legislation prohibits the use of any constituent or additive that causes a cigarette or its smoke to have a characterizing flavor other than tobacco. The measure exempts menthol-flavored cigarettes, however, from this prohibition. The restriction would apply to such flavors as "Mandalay Lime," "Warm Winter Toffee," "Mocha Taboo," and "Midnight Berry." In its report, the House Energy and Commerce Committee noted that this provision is "not intended to prohibit the use of specific ingredients, including those found in some American blend cigarettes, so long as those additives or constituents are not a characterizing flavor (other than tobacco or menthol) of the cigarette or its smoke." A cigarette could not be determined to have a prohibited characterizing flavor based solely on the presence of an ingredient in the product or its smoke.

Furthermore, the House committee noted the "unique issues" surrounding menthol cigarettes and urges the FDA to address these issues "as quickly as practicable." The committee specifically expressed concern about proportionately higher rates of menthol cigarette use among African-Americans, as well as the "historic targeting of African-Americans for menthol cigarette use by tobacco companies."

Tobacco Product Standard

The finalized bill allows the FDA to adopt a product standard for tobacco products if it determines that such a standard is appropriate for the protection of public health. The standard could include provisions to alter nicotine yields, to reduce or eliminate other constituents or harmful components, and labeling of the tobacco product.
In addition, the FDA is required to periodically review the product standards, and consider new medical, scientific, or other technological information. In issuing rules, the agency would be required to consult with other federal agencies. The FDA could also refer a proposed rule to the Tobacco Products Scientific Advisory Committee for collecting additional data and creating a report on the issue, which must then be made public.

Notification & Recall of Tobacco Products

Moreover, the FDA is authorized to make public service announcements relating to tobacco products if those products present an "unreasonable risk of substantial harm," as notification is the most practicable means available to address a health risk. Under the bill, the FDA could recall a tobacco product if it contains a defect that would cause serious adverse health consequences or death and is not normally contained in tobacco products on the market.

Submission & Publication of Health Information

Content Descriptions

The measure requires — within six months of enactment — manufacturers to submit to the FDA a list of ingredients, compounds, substances, and additives in their cigarettes. It also requires a description of the content, delivery, and form of nicotine, as well as documents developed after enactment relating to health, toxicological, behavioral, or physiologic effects of tobacco products. This information would be required of all current tobacco products as well as any tobacco products introduced after enactment.

Written Notice of New Additive

Manufacturers must submit a written notice to the FDA at least 90 days prior to marketing if the manufacturer adds a new additive to its product or increases the amount of an additive. It also requires a written notice at least 60 days prior to marketing if a tobacco manufacturer eliminates or decreases an existing additive.

List of Harmful Ingredients

The FDA is required, within three years of the legislation's enactment and annually thereafter, to publish a list of harmful and potentially harmful constituents in each brand. The measure also requires the FDA to conduct consumer research to ensure that publication of the list is not misleading. After five years, the agency would report to Congress on the results of that

research, and provide a recommendation on whether or not to revise the list.

Registration of Tobacco Manufacturers

This legislation mandates the registration of every entity engaged in the manufacture, preparation, compounding, or processing of tobacco products. It extends the requirement to foreign establishments. Once registered, every establishment would be subject to an inspection by the FDA once every two years.

Adulterated Tobacco Products

The bill establishes specific guidelines for determining whether tobacco products are adulterated. Tobacco products manufactured, packed, or stored in unsanitary conditions would be deemed adulterated. In addition, a product would be deemed adulterated if its manufacturer fails to pay required user fees, or if it does not meet the product standards established for the product.

Additionally, the measure authorizes the FDA to require tobacco manufacturers and importers to establish and maintain records and submit them to the agency, to ensure that tobacco products are not adulterated or misbranded. The FDA could also require manufacturers and importers to report serious unexpected adverse reactions caused by the use of a tobacco product.

Application for Review

Premarket review is established for all new tobacco products entering the market, unless the FDA determines that the product is "substantially equivalent" to an existing product. Under the measure, products would be considered substantially equivalent if they have the same characteristics as a marketed product, or have different characteristics, but do not raise "different public health questions."

Application Content Requirements

Each application must contain all information published or known to the applicant relating to studies on the health risks of the product. The application would also be required to include a listing of ingredients; how the product is operated or used; a description of the methods employed to manufacture a product; and samples of the product and the product's proposed labeling.

Denial of an Application

The measure mandates that the FDA, within 180 days of enactment, make a determination of whether to allow the new product to enter the market or deny the application. The FDA could deny the application if the agency finds that the applicant has not shown that marketing of the product would be appropriate for the protection of the public health, or that the making of the product did not conform to good manufacturing practices, or if the labeling is false or misleading.

Modified Risk Tobacco Products

Labeling

Furthermore, the measure bars the selling or distributing of a modified-risk tobacco product without having obtained an order pertaining to the product from the FDA. The measure defines the sale or distribution of these products as including labeling or advertising that states or implies that the product presents a reduced risk of harm or of tobacco-related disease; or that there is reduced exposure to a substance; or that uses the words "light," "mild," or "low." The measure clarifies that the use of the following phrases in advertising a product does not constitute a reduced-harm claim: "smokeless tobacco;" "smokeless tobacco products;" "not consumed by smoking;" "does not produce smoke;" "smoke-free;" "without smoke;" "no smoke;" or "not smoke."

Authorizing Commercial Marketing

The measure provides that the FDA must issue an order so that a product may be commercially marketed. This order would be issued only if the agency determines that the applicant has demonstrated that the product will significantly reduce harm and the risk of tobacco-related disease to individual users.

Regulations & Guidelines

The measure requires the FDA, within two years of enactment, to issue guidance or regulations on the scientific evidence required for assessment and ongoing review of modified-risk tobacco products. The FDA would develop those regulations or guidelines in consultation with the Institute of Medicine.

Judicial Review

The measure allows individuals adversely affected by FDA regulations relating to performance standards or premarket review to file, within 30 days, a petition for judicial review with a federal court of appeals. These remedies would be in addition to, not in lieu of, any other remedies provided by current law. Judgment by the appellate court would be final, subject to review by the Supreme Court.

Testing & Reporting Regulations

The Senate amendment requires the FDA, within 36 months of enactment, to issue regulations that mandate the testing and reporting of tobacco product smoke ingredients and additives that the agency has determined should be tested in order to protect public health.

Compliance of Small Tobacco Manufacturers

The measure allows the FDA to delay testing and reporting requirements for four years. The FDA could also delay the deadline for testing and reporting on a case-by-case basis.

Scientific Advisory Committee

The bill establishes a 12-member advisory committee representing the public, tobacco growers, the health community, and tobacco manufacturers. The committee would be required to include one member representing the interests of small manufacturers. The committee would provide advice and guidance to the FDA on the effects of altering nicotine yields from tobacco products. It would also advise the FDA on the threshold level at which nicotine becomes addictive and other health issues as requested by the agency.

Products Treating Tobacco Dependence

The FDA must report to Congress within three years on ways to regulate and development products that promote abstinence from tobacco use, reductions in consumption, and reductions in the harm associated with tobacco use.

Cost Offset

The Health and Human Services Department must assess user fees on manufacturers and importers of tobacco products. The fees would be assessed and collected with respect to each quarter of each fiscal year. The legislation allows the FDA to obligate the collected fees only to the extent, and in the amount, provided in advance through appropriations laws.

The measure authorizes the appropriation of assessments equal to $85 million in FY 2009, $235 million in FY 2010, $450 million in FY 2011, gradually increasing amounts that would reach $712 million in FY 2019. Assessments would continue at that level after FY 2019. The legislation also requires the automatic enrollment of newly-hired eligible federal employees and members of the uniformed services in the Thrift Savings Plan. It sets contributions of new participants at 3% of their basic pay. These participants would have the option of modifying the contribution percentage or completely declining enrollment. Furthermore, the bill gives the

Federal Thrift Retirement Investment Board the authority to establish a Roth contribution plan and self-directed investment options within the Thrift Savings Plan.

Born and raised in Delaware County, former 3-star Admiral Joe Sestak served in the Navy for 31 years and now serves as the Representative from the 7th District of Pennsylvania. He led a series of operational commands at sea, including Commander of an aircraft carrier battle group of 30 U.S. and allied ships with over 15,000 sailors and 100 aircraft that conducted operations in Afghanistan and Iraq. After 9/11, Joe was the first Director of "Deep Blue," the Navy's anti-terrorism unit that established strategic and operations policies for the "Global War on Terrorism." He served as President Clinton's Director for Defense Policy at the National Security Council in the White House, and holds a Ph.D. in Political Economy and Government from Harvard University. According to the office of the House Historian, Joe is the highest-ranking former military officer ever elected to the U.S. Congress.

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